UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,697	02/10/2004	Richard A. Couch	20342/1202658-US2	7361

7278 7590 06/19/2008

DARBY & DARBY P.C.
P.O. BOX 770
Church Street Station
New York, NY 10008-0770

EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,697	COUCH ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18-21 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18-21 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16, 18-21 and 24-29 are presented for examination.

Applicant's Amendment filed March 19, 2008 has been received and entered into the present application.

Claims 1-16, 18-21 and 24-29 are pending and under examination. Claim 29 is newly added, claims 1 and 24-26 are amended and claims 17 and 22-23 are cancelled.

Applicant's arguments and amendments, filed March 19, 2008, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16, 18-21 and 24-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth at pages 4-9 of the previous Office Action dated November 19, 2007, of which said reasons are herein incorporated by reference.

Newly added claim 29 is properly included in the present rejection because it further limits the pharmaceutical combination of claim 1 used in the method for treating ADHD (as defined in instant claim 27) to a combination that comprises two unit doses of amphetamine, wherein the first unit dose having an

l to d isomer ratio of about 1:3 or contains only d isomer, and the later unit dose having an l to d isomer ratio of greater than 1:1 or contains l isomer only. In other words, present claim 29 is directed to a method for treating ADHD by administering a specific embodiment of the pharmaceutical combination claimed and described in instant claim 1, which comprises an effective amount of l- and d-amphetamines, wherein the molar ratio of l-amphetamine to d-amphetamine released from the pharmaceutical combination in a time period later in the day is higher than the ratio released therefrom in a time period earlier in the day. In view of the fact that claim 29 fails to cure the deficiencies in written description with regard to the limitation directed to the molar ratio of l-amphetamine to d-amphetamine released from the pharmaceutical combination in a time period later in the day being higher than said ratio released therefrom in a time period earlier in the day, newly added claim 29 also lacks adequate written description for the same reasons already provided at pages 4-9 of the previous Office Action dated November 19, 2007, which are herein incorporated by reference and will not be repeated herein so as not to burden the record.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that the claimed invention calls for a composition that results in a specific release profile of amphetamines during the day rather than a particular sustained/delayed release combination and submits that the claimed release profile could be achieved by any number of sustained/delayed release formulations that a skilled artisan would be able to produce with knowledge that is well known in the art. Applicant further states that it is unnecessary to recite specific compositions that result in this release profile and refers to the numerous descriptions of exemplary formulations that are capable of achieving the claimed release profile as evidence that the release profile as claimed can be achieved by a variety of combinations. Still further, Applicant insists that none of the

disclosed formulation types are essential to obtain the claimed release profile and again alleges that a variety of different formulations may be used and are all conventional and well known in the art.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, it is agreed that the manner in which the instant claims are presently written do contain a limitation directed to a specific release profile of the l- and d-amphetamines contained therein over the course of the day. However, while it may very well be true that such a claimed release profile may be achieved by using any number of sustained/delayed release formulations that are conventional and well known in the art, the fact remains that Applicant has simply described generic technologies (such as, *inter alia*, extended release tablets, pulsing techniques using enteric coatings, osmotic systems, layered bead formulations, immediate release formulations, etc.) that could be employed to effect the instantly claimed function of releasing a higher ratio of l-amphetamine to d-amphetamine in a time period later in the day than the ratio released therefrom in a time period earlier in the day, without ever adequately describing the specific structure(s), material(s) or act(s) that are responsible for effecting the function of the combination as instantly claimed and/or that may be used to achieve the instantly claimed function of the combination. It is this element that is clearly and conspicuously missing from the instant specification and, therefore, indicates that Applicant was not, in fact, in possession of the full scope of subject matter now claimed because there is no indication that Applicant himself actually identified those specific structures, materials or acts that operate to accomplish the instantly claimed release profile.

In addition, it is strongly disputed that the specific formulation type is *not* essential for achieving the claimed release profile. Applicant has continued to allege that the instantly claimed release profile is a patentably distinguishing characteristic of the instantly claimed invention, but has conspicuously failed to describe how exactly one could employ known and conventional formulations to actually accomplish the release profile instantly claimed. In the absent of this description or guidance, Applicant has set forth no more than a *plan* for how to formulate the claimed combination of l- and d-amphetamine for use in the

presently claimed invention, but has not actually shown possession of the invention as claimed. In other words, the specification lacks a complete and/or adequate description of how these disclosed generic technologies operate to achieve the claimed function in such a manner such that the skilled artisan would have recognized that these specific types of formulations were capable of functioning in the manner instantly claimed.

The issue here at hand is not of "undue experimentation", but rather that, out of all of these same disclosed or possible formulations that may be used, Applicant has failed to clearly demonstrate, on the record, that he was, in fact, in possession of any one or more *specific formulations that were operable to achieve the release profile as instantly claimed.* Without such a disclosure of even a single formulation that functions to achieve the claimed combination of l- and d-amphetamines wherein the molar ratio of l-amphetamine to d-amphetamine released from the pharmaceutical combination in a time period later in the day is higher than said ratio released therefrom in a time period earlier in the day, it is clear that Applicant may very well have had a *plan* to obtain the combination as claimed, but was not in possession of even one identified formulation that, in fact, was operable to function in the manner claimed. As previously stated, a wish or plan for obtaining the invention as claimed does *not* provide adequate written description of the invention as a whole because it places the burden on the skilled artisan to extensively test numerous different formulations to arrive at even one single formulation that performs the function claimed. The need for identifying the specific structure, material or acts necessary to achieve the claimed function is clear evidence that Applicant lacked possession of the full scope of subject matter instantly claimed because Applicant cannot logically be in possession of that which he has yet to identify at the time of the invention (which, in the instant case, is the specific type of formulation that achieves the claimed release profile). Furthermore, this need for adequate written description is *not* satisfied by Applicant's diffuse reference to various conventional and known formulations because it does not

eliminate the need to undertake hit or miss testing among all such conventional and known formulations to identify even one formulation that would work in the manner claimed.

Lastly, while it is agreed that a patent specification need not teach, and preferably omits, what is well known in the art, such an argument is similarly unpersuasive in establishing possession of the full scope of the claimed subject matter because Applicant has failed to specifically point out how the state of the art was sufficiently well-developed that one of skill in the art would have immediately envisaged the structure, material or acts that would function to elicit the release profile as instantly claimed. Without this information, one of ordinary skill in the art at the time of the invention would have had no alternative recourse but to sort through hundreds of various formulation types to arrive at even one single formulation that is operable to achieve the claimed function. This need for extensive testing fails to satisfy the requirements of 35 U.S.C. 112, first paragraph, which requires the specification to contain a written description of the invention, because it fails to specifically and particularly describe the essential feature that effects that claimed release profile. Furthermore, it has long been held that an applicant for patent must fully and completely describe the subject matter contained in the claims in order to obtain a patent on the claimed invention; in the absence of a full and complete description of the claimed elements of the invention in a manner sufficient to reasonably apprise one of skill in the art of the manner and processing of making and using said invention, the claims fails to meet the written description requirement of 35 U.S.C. 112, first paragraph.

For these reasons *supra*, and those previously made of record at pages 4-9 of the Office Action dated November 19, 2007, rejection of claims 1-16, 18-21 and 24-29 is proper.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 14 is directed to the pharmaceutical combination of claim 1, which is a combination comprising an effective amount for a day of l- and d-amphetamines, each in base and/or salt form, and wherein the molar ratio of l-amphetamine to d-amphetamine released form the pharmaceutical combination in a time period later in the day is higher than said ratio released therefrom in a time period earlier in the day, and wherein the combination provides greater than one dosage form, wherein a single dosage form provides amphetamine release in both of said earlier and later periods.

In particular, it is unclear how a single dosage form of l- and d-amphetamine may be used to provide amphetamine release in both said earlier and said later periods as stated in instant claim 14, when independent claim 1 specifically and particularly requires that greater than one dosage form is employed in the pharmaceutical combination. Accordingly, the required limitation of instant claim 14 is inconsistent with the requirements of independent claim 1 and, therefore, renders the scope of the claim indefinite. As a result, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the metes and bounds of the subject matter for which Applicant is presently seeking protection.

For these reasons, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and is, thus, properly rejected.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 26 is directed to the pharmaceutical combination as described in claim 2, wherein the second unit dose contains l-isomer only.

In particular, there is insufficient antecedent basis for the limitation "the second unit dose" in lines 1-2 of claim 26, since neither claim 25 nor claim 1 from which claim 26 depends sets forth any reference to a "second unit dose" *per se*.

For these reasons, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and is, thus, properly rejected.

For the purposes of examination, the limitation "the second unit dose" as recited in claim 26 will be interpreted to refer back to the "later unit dose" as described in instant claim 25.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16, 18-21 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patrick et al. ("Pharmacology of Methylphenidate, Amphetamine Enantiomers and Pemoline in Attention-Deficit Hyperactivity Disorder", 1997; p.527-546) in view of Epstein et al. (WO 2002/039998; 23 May 2002), Burnside et al. (U.S. Patent No. 6,322,819; 2001), STN Registry File (Registry No. 156-34-3) and

Tulloch et al. ("SLI381 (Adderall XR), a Two-Component, Extended Release Formulation of Mixed Amphetamine Salts: Bioavailability of Three Test Formulations and Comparison of Fasted, Fed and Sprinkled Administration, *Pharmacotherapy*, 2002; 22(11):1405-1415), each already of record, for the reasons of record set forth at pages 14-18 of the previous Office Action dated November 19, 2007, of which said reasons are herein incorporated by reference.

Newly amended claim 1 and newly added claim 29 are properly included in the present rejection because newly amended claim 1 now requires the combination to provide at least one dosage form and newly added claim 29 further limits the pharmaceutical combination of claim 1 used in the method for treating ADHD (as defined in instant claim 27) to a combination that comprises two unit doses of amphetamine, wherein the first unit dose having an l to d isomer ratio of about 1:3 or contains only d isomer, and the later unit dose having an l to d isomer ratio of greater than 1:1 or contains l isomer only. This manner of administration is clearly suggested by the prior art teachings of Patrick et al. in view of Epstein et al. (see, e.g., p.12-13 of the Office Action dated October 20, 2006), which clearly teaches that the l-isomer of amphetamine was known to have enhanced efficacy and reduced side effects (i.e., addiction) and compositions of both the l-isomer (either enriched for l-isomer or containing l-isomer alone), as well as composition of the l- and d-isomers with more d- than l-isomer, were both known in the art for the treatment of ADHD (see Patrick et al., p.536-538 and Epstein et al., p.16, l.6-15). Therefore, the administration of a combination of these two known compositions (i.e., providing greater than one dosage form as in instant claim 1), in either order, would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention because each was known to be effective for the same therapeutic purposes and, thus, would have been expected to achieve additive, if not synergistic, ADHD-reducing side effects when combined. Please see *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that the molar ratio release profile called for in the instant claims is a claim limitation and that the many different compositions and dose administrations that may be used to arrive at the claimed release profile are not essential and do not need to be recited in the instant claims. Applicant further alleges that the cited references would not have led a reasonable person to predict that the cited prior art would have yielded nothing more than the claimed release profile and, thus, the instant claims are not obvious over the cited prior art.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant is again reminded that the instant claims, as presently written, fail to set forth the particular structure(s), material(s) or act(s) that are responsible for the pharmaceutical combination to function in the manner claimed (i.e., to release a molar ratio of l-amphetamine to d-amphetamine in a time period later in the day that is higher than the ratio released therefrom in a time period earlier in the day). Applicant's attention is again directed *supra* to the discussion presented under 35 U.S.C. 112, first paragraph, which describes the reasons behind this assertion.

In view of this fact, Applicant's failure to explicitly set forth the physical structure(s), material(s) or element(s) *in the claims* that are essential to effecting the claimed function (or even to adequately describe it in the accompanying specification) is clearly indicative of the fact that the claims *per se* fail to distinguish themselves over a physical and structural combination of both l-amphetamine and d-amphetamine, each in base and/or salt form. Despite the recited release profile of the claimed combination, the claims do not specify the particular structural elements responsible for this function and, therefore, the claimed release of the composition fails to patentably limit the actual physical combination of both l- and d-amphetamine, since the only required physical components of the claimed combination are the l- and d-amphetamines, each in base and/or salt form. Furthermore, though Applicant appears to be of the persuasion that such structure(s), material(s) or act(s) are *not* essential to the claimed invention,

the basis of this assertion is unclear because Applicant has repeatedly alleged that the instantly claimed release profile is a patentably distinguishing characteristic of the instantly claimed property. In other words, if Applicant alleges that the point of novelty and unobviousness of the instantly claimed invention lies in that the claimed combination (and methods of use thereof) releases the l- and d-amphetamine in the manner instantly claimed, then such a profile is clearly essential to the claims and must be adequately described both in the instant specification and claims so as to distinguish the claimed combination (and methods of use thereof) from a simple combination of l- and d-amphetamine in base and/or salt form.

Accordingly, it is properly maintained herein that the claimed function directed to "wherein the molar ratio of l-amphetamine to d-amphetamine released from the pharmaceutical combination in a time period later in the day is higher than said ratio released therefrom in a time period earlier in the day" is not patentably limiting to the claimed pharmaceutical combination. In light of this fact, the claims remain properly rejected over the prior art of record for the reasons originally set forth at p.9-13 of the previous Office Action dated October 20, 2006 (and further in view of the additional reasons provided in the previous Office Actions dated May 16, 2007 and November 19, 2007), and further relying upon the guidance provided at MPEP §2112.01, which states, "Where the claimed and prior art products are identical or substantially identical *in structure or composition*, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established...Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. *Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present.*" (emphasis added) Such reasons will not be repeated herein so as not to burden the record, but are hereby incorporated by reference.

For these reasons *supra*, and those previously made of record at pages 14-18 of the Office Action dated November 19, 2007, rejection of claims 1-16, 18-21 and 24-29 is proper.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 and 24-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the composition claims of U.S. Patent Nos. 6,605,300; 6,322,819l or 6,913,768; and are provisionally rejected over the composition claims of U.S. Patent Application Nos. 11/091,011; 10/758,417; or 11/030,174, each already of record, for the reasons of record set forth at p.18-19 of the previous Office Action dated November 19, 2007, of which said reasons are herein incorporated by reference.

Cancellation of claims 22-23 renders the instant rejection moot as applied to such claims.

Newly amended claim 1 remains properly included in the present rejection because the claim has been amended to now require the combination to provide greater than one dosage form. In view of the fact that the subject matter of instant claim 13 has already been addressed in the context of the present obviousness-type double patenting rejections (wherein claim 13 requires two separate dosage forms, one for use in the earlier period of the day and one for use in the later part of the day), this newly added limitation to instant claim 1 now requiring more than one dosage form is also obvious for the same reasons that instant claim 13 is obvious over the cited copending applications and/or patents.

In view of the fact that Applicant presents no arguments of Terminal Disclaimers regarding the obviousness-type double patenting rejections of record, the rejections remain proper for the reasons set forth at pages 18-19 of the previous Office Action dated November 19, 2007 and are, therefore,

maintained.

Conclusion

Rejection of claims 1-16, 18-21 and 24-29 is proper.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

June 12, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614